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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--------------------------|---------------------|------------------|
| 10/526,282   | 02/16/2006  | Cindy Maree Baulch-Brown | ON/4-32665A         | 6233             |
| 1095 7590 12/05/2008   |             |                          |                     |                  |
| NOVARTIS<br>CORPORATE INTELLECTUAL PROPERTY<br>ONE HEALTH PLAZA 104/3<br>EAST HANOVER, NJ 07936-1080 |             |                          |                     |                  |
| EXAMINER   |             |                          |                     |                  |
| SZNAIDMAN, MARCOS L  |             |                          |                     |                  |
| ART UNIT   |             | PAPER NUMBER             |                     |                  |
| 1612   |             |                          |                     |                  |
| MAIL DATE  |             | DELIVERY MODE            |                     |                  |
| 12/05/2008   |             | PAPER                    |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/526,282

**Applicant(s)**

BAULCH-BROWN ET AL.

**Examiner**

MARCOS SZNAIDMAN

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5, 6, 14, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 5, 14 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)  
Paper No(s)/Mail Date 4 pages / 07/27/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to applicant's reply filed on August 21, 2008.

#### ***Election/Restrictions***

Applicant's election of Group 1 (claims 1 and 6-9) in the reply filed on August 21 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Status of Claims***

Addition of claims 17 and 18, cancellation of claims 7-13 and 15-16, and amendment of claims 1, 5-6 is acknowledged

Claims 1, 5-6, 14, and 17-18 are currently pending and are the subject of this office action.

Claim 5, 14 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 21, 2008.

Claims 1, 6, and 17 are presently under examination.

#### ***Priority***

The present application is a 371 of PCT/EP03/09972 filed on 09/08/2003, and claims benefit to foreign application UK 0220885.8 filed on 09/09/2002.

***Information Disclosure Statement***

The Information Disclosure Statement filed on July 27, 2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fisher et. al. (WO 1999/45923, cited by applicant).

Claims 1, 6 and 17 recite a pharmaceutical composition comprising: a bisphosphonate and an HMG-CoA reductase inhibitor (fluvastatin in claim 17), wherein the bisphosphonate is zoledronic acid or a pharmacologically acceptable salt thereof.

For claims 1, 6 and 17, Fisher et. al. teach (see claims 16-19) a pharmaceutical composition comprising: a HMG-CoA reductase inhibitor, fluvastatin in particular (see claim 18) and a bisphosphonate, zoledronate in particular (see claim 19).

The statements in claim 1: "for the treatment of malignancies", and claim 6: "for the inhibition of cancer cell growth or induction cancer cell apoptosis" are considered

intended uses and do not add any new limitation to the claims. Catalina Mktg. Int'l, Inc. V. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). "The recitation of a new intended use for an old product does not make a claim to that old product patentable." In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

### ***Conclusion***

No claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
November 24, 2008

/Brandon J Fetterolf/  
Primary Examiner, Art Unit 1642